

REMARKS/ARGUMENTS

The final Office Action of June 9, 2009 has been carefully reviewed and this paper is Applicants' response thereto. Claims 1-13, 16-19, 21-29, 32, 35-37 and 39-40 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Whitehurst, U.S. Patent Application No. 2002/0013612 ("Whitehurst"). Claims 30-31 and 33 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, as obvious over Whitehurst. Claim 34 was rejected under 35 U.S.C. §103(a) as being unpatentable over Whitehurst. Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Whitehurst, in view of Haller, et al., U.S. Application No. 2002/0013613 ("Haller"). In response, Applicants respectfully traverse the rejections in view of the above amendments to the claims and the following remarks.

Independent claims 1, 11, 37, 39 and 40, and dependent claims 21, 23 and 31 have been amended to clarify the invention. Claims 14, 15, and 38 were previously canceled as their subject matter has been added to existing claims. Claims 1-40 stand rejected.

Rejection under 35 U.S.C. 112, second paragraph

Claims were rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1 and 11 were deemed vague because the implantable device had not been set forth to operate in a closed-loop mode, only the external device. Claims 1 and 11 have been amended. Claim 1 has been amended to claim "a first external component configured to receive data from the implantable component and to provide an instruction to the implantable component to operate in a second treatment therapy mode in accordance with the data" Claim 11 has been amended to claim "an external component configured to receive data from the implantable component, the external component comprising a first module that provides an instruction to the implantable component to operate in a second treatment therapy mode when the external component is coupled to the implantable component." In view of there amendments, it is respectfully submitted that the rejection under 35 U.S.C. 112, second paragraph has been rendered moot, and should be withdrawn.

Rejection under 35 U.S.C. 102(e)/103(a)

Independent Claim 1

Independent claim 1, as amended, recites the feature of an “an implantable component configured for multi-modal operation, the implantable component configured to provide the treatment therapy in a first treatment therapy mode, wherein the first treatment therapy mode corresponds to an open-loop control mode” (emphasis added). Additionally, amended claim 1 recites the feature of “a first external component configured to receive data from the implantable component and to provide an instruction to the implantable component to operate in a second treatment therapy mode in accordance with the data, wherein the second treatment therapy mode corresponds to a closed-loop control mode” (emphasis added).

Whitehurst discloses a system or method for introducing drugs or electrical stimulation to the brain to treat mood and/or anxiety disorders. (Whitehurst, Abstract). The system includes an implantable system control unit (SCU). (Whitehurst, Abstract). Whitehurst states that the system may be capable of both open- and closed-loop operation. (Whitehurst, Abstract). According to one embodiment, the implantable SCU operates independently. (Whitehurst, para. [0081]). According to another embodiment, the implantable SCU may operate in a coordinated manner with an external component, such as another implantable SCU, other implanted devices, or other devices external to the patient’s body. (Whitehurst, para. [0081]). Whitehurst discloses that the external component may perform the following functions: sending commands and/or data to an SCU (para. [0081]), receiving commands and/or data from an SCU (para. [0081]), programming or diagnostic purposes (para. [0082]), programming and providing power to SCU (para. [0083]).

The Applicants respectfully submit that the external component as disclosed in Whitehurst does not provide an instruction to the implantable component to operate in a second treatment therapy mode in accordance with data as recited in claim 1. Whitehurst merely discloses that the external component sends or receives command, programs, performs diagnostics or provides power to the SCU. Whitehurst does not provide the separate feature of providing an instruction to the implantable component to operate in a second treatment therapy mode in accordance with data, let alone disclose an instruction to the implantable component to

operate in a closed loop control mode, as claimed in claim 1, as amended. Additionally, in Whitehurst, as stated in the Office Action, “Whitehurst discloses a system and method for treating mood or anxiety disorders, which is a nervous system disorder, by stimulating the brain utilizing an implantable system control unit (SCU), electrodes and a pulse generator for treatment.” (final Office Action, pg. 5) (emphasis added). Employing an external component in a closed-loop mode in Whitehurst is **not** the same as the external component configured to provide an instruction to an implantable component to operate in a second treatment therapy mode in accordance with the data [from the implantable component], wherein the second treatment therapy mode corresponds to a closed-loop control mode as claimed in amended claim 1.

Additionally, Applicants respectfully traverse the Examiner’s arguments regarding Whitehurst’s disclosure of the automatic switching between the open-loop treatment and closed-loop treatment. Applicants respectfully assert that Whitehurst does not disclose the automatic switching as recited in claim 1.

Independent claim 1 recites the feature of “wherein the implantable component is configured to operate in the open loop control mode when the external component is decoupled from the communications channel and to automatically switch to the closed loop control mode when the external component is coupled to the communications channel” (emphasis added). Once again, in support of the rejection, the Office has pointed to paragraph 92 of Whitehurst disclosing: “external electronic appliance 230 may include an automatic algorithm that adjust electrical and/or drug stimulation parameters automatically whenever the SCU(s) 130 is/are recharged.” (final Office Action, pg. 6). The examiner then concludes, “Therefore, Whitehurst discloses the automatic switching between open and closed loop function with the SCU(s).” (final Office Action, pg. 6). However, the Applicants assert that this portion of Whitehurst fails to disclose any automatic switching between a closed- and open-loop function within the implantable component or medical system, but merely discloses an external component that is configured to “adjust . . . parameters” for a treatment mode during charging, and nothing more. While there is the use of the words, “automatic,” and “automatically,” this portion of Whitehurst does **not** refer to automatic switching between a closed- and open-loop control mode upon coupling or de-coupling of an external component to a communications channel, but in contrast,

automatic changing of parameters in a single treatment mode during charging. The Applicants respectfully submit that these are not the same.

Additionally, the final Office Action cites to paragraph 90 on page 8 of Whitehurst as further evidence of automatic switching between closed- and open-loop control. The Office Action concludes, "Therefore, since there are two modes of operation, closed loop and open loop, there would necessarily be an automatic mode of switching between them." The Applicants respectfully traverse this statement. While Whitehurst states that its system is capable of open- and closed-loop operation (*see* Whitehurst, Abstract), Applicants submit that claim 1 recites specifically that the automatic switching occurs when the external component is coupled or decoupled from the implantable device. This requirement is not disclosed in Whitehurst. Whitehurst merely discloses that there are two modes, an open and closed mode, and not how or when they switch from each of the two different modes.

Lastly, the Office Action suggests that it would be obvious to include a switching mode. The Applicants, however, respectfully submit that the Office Action fails to provide any rationale for why the system of Whitehurst should be so modified or what the basis for such a modification would be. In particular, there is no disclosure for how the programming or re-programming would be done by a user and could be done automatically. Instead, it appears that Whitehurst merely discloses the ability to couple an external component to an implanted device and modify parameters of the implanted device, but fails to disclose the feature of automatically switching between the open- and closed-loop modes.

Therefore, for at least the above reasons, Whitehurst fails to disclose, suggest, or teach all the features of amended claim 1. Accordingly, amended claim 1 is patentable over Whitehurst.

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007). It is respectfully submitted that the final Office Action does not provide "articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness" as required by *KSR*. Applicants respectfully request that if the §103 rejection is maintained, or if further rejections are set forth, that the Office provide an analysis of obviousness that considers

the *Graham* factors so the Applicants may more readily respond to any assertions of obviousness.

Dependent Claims 2-10

Claims 2-10, which depend from claim 1, are patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein.

Claims 11 and 12

Independent claim 11 recites features similar to the above features of claim 1, thus Whitehurst also fails to disclose at least those features of this independent claim. Therefore, claim 12, which depend from claim 11, is patentable for at least the reasons that claim 11 is patentable and for the additional features recited therein.

Claims 13, 16-36

Independent claim 13 recites features similar to the above features of claim 1, thus Whitehurst also fails to disclose at least those features of this independent claim. Therefore, claims 16-36, which depend from claim 13, are patentable for at least the reasons that claim 13 is patentable and for the additional features recited therein.

Independent Claim 37

Independent claim 37 recites features similar to the above features of claim 1, thus Whitehurst also fails to disclose at least those features of this independent claim. Therefore, claim 37 is patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein.

Independent Claim 39

Independent claim 39 recites features similar to the above features of claim 1, thus Whitehurst also fails to disclose at least those features of this independent claim. Therefore, claim 39 is patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein.

Independent Claim 40

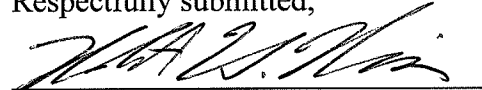
Independent claim 40 recites features similar to the above features of claim 1, thus Whitehurst also fails to disclose at least those features of this independent claim. Therefore, claim 40 is patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein.

CONCLUSION

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

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Respectfully submitted,



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